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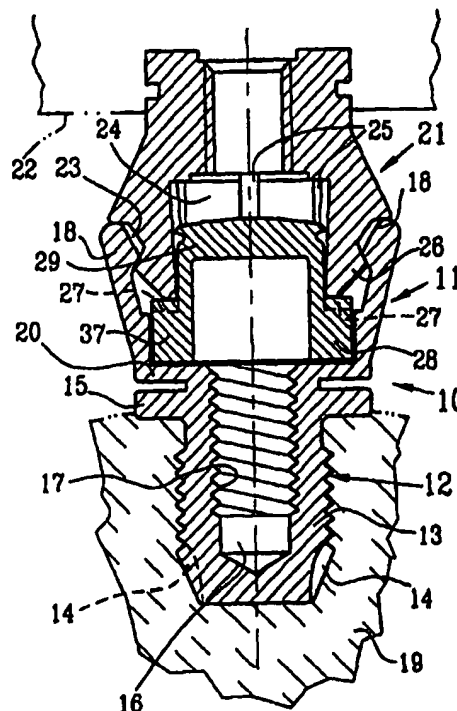
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(21) International Application Number: PCT/SE98/01049 (22) International Filing Date: 2 June 1998 (02.06.98) (30) Priority Data: 9702164-6 6 June 1997 (06.06.97) SE (71) Applicant (for all designated States except US): P & B RE-SEARCH AB [SE/SE]; Hörsalsvägen 9, S-412 96 Göteborg (SE). (72) Inventors; and (75) Inventors/Applicants (for US only): HÅKANSSON, Bo [SE/SE]; Splintvedsgatan 7, S-416 80 Göteborg (SE). CARLSSON, Peder [SE/SE]; Prästvågen 7649, S-442 93 Kungälv (SE). (74) Agent: GÖTEBORGS PATENTBYRÅ; Sjöporten 4, S-417 64 Göteborg (SE).			(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments. In English translation (filed in Swedish).

(54) Title: A DEVICE FOR ANCHORING AND ENERGY TRANSFER AT IMPLANTS

(57) Abstract

A device at implants (10) for anchoring in bone tissue (19) and supporting a prosthesis or transfer of electrical and/or mechanical energy from a transmitter (22) or the like to the implant via a coupling device, which incorporates a first and a second coupling part. The implant (10) which incorporates a flange fixture (13) is made integral with the first coupling part (11), forming a continuous unit therewith.



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A DEVICE FOR ANCHORING AND ENERGY TRANSFER AT IMPLANTS

5

TECHNICAL FIELD

The present invention refers to a device at implants for anchoring in bone tissue and supporting of a prosthesis or transfer of electrical and/or mechanical energy from a transmitter or the like to the implant via a coupling device, which incorporates a first and a second
10 coupling part.

BACKGROUND AND TECHNICAL PROBLEM OF THE INVENTION

An example of such implants is for instance skull bone anchored implants for transfer of signals from a hearing aid connected to the implant. More specifically the invention can
15 constitute a development of the device described in SE-C2 503790.

For such applications today is used a two-piece implant, the parts of which are affixed to each other by means of a screw joint. One part of the implant consists of a threaded element, which is anchored in the bone tissue and the second part is a socket, which penetrates the soft tissue.
20 The reason for the implant used today to be in two pieces is i.a. that the surgical technique used today requires an operation made in two steps. In the first step, the threaded element or the bone screw is installed. This is thereupon allowed to heal up during a time period of several months without being subjected to any external stresses during that time. Not until
25 after this healing period the second part of the operation is carried through, whereby the external skin penetrating socket is installed.

Furthermore the mutual rotational affixing between the bone anchored inner element and the skin penetrating outer part can be adjusted, which is necessary at certain types of couplings, such as bayonet couplings. In case of possible, more serious skin irritations, the outer socket
30 can be removed without influencing the bone anchored element.

The connecting screw is also acting as an overload protection, which can be designed to burst at heavy, external mechanical stresses, in order not to risk that the healed up, bone anchored element shall be broken away.

35

Due to the two-piece design it is possible to up-grade the coupling device used without need of removal of the bone screw, and if the external skin penetrating socket is damaged it is also possible to exchange it without influence on the bone screw.

- 5 If the patient finally is not satisfied with the member connected to the implant (e.g. a hearing aid), the intact skin can be restored without need for removal of the bone anchored element.

A problem connected to the hitherto used two-piece implants is that the manufacturing costs will become rather high, on one hand due to the number of parts, i.e. bone screw, outer socket, connecting screw, and often also sealing and covering members, and on the other hand due to
10 the requirement for very high tolerances for the internal fitting of the parts concerned, in particular for signal transferring applications.

PURPOSE OF THE INVENTION AND SOLUTION OF THE PROBLEM

15

The purpose of the present invention is to create an implant of the type mentioned in the introductory part, which:

- . has a lower height and therefore is less subjected to external influence,
 - . consists of fewer elements,
 - 20 . is simpler and less expensive to manufacture with lower demand for high tolerances,
 - . has a lower frequency of skin irritation,
 - . simplifies the surgical procedure and cuts the healing time substantially,
 - . shall have ability to take up a certain external force without the implant coming loose.
- 25

Furthermore the advantages inherent in the known implant shall be maintained or even be improved, which means:

- . that at more serious cases of skin irritation or at damages on the skin penetrating outer part, it shall be possible to remove this without influencing the
30 inner, bone anchored part,
- . that interconnection function by means of a snap action connection and disconnection by means of a turning motion is maintained.

These tasks have been solved by the features defined in the claims.

DESCRIPTION OF THE DRAWINGS

5 Hereinafter the invention will be described more in detail in some embodiments with reference to the accompanying drawings.

Fig. 1 shows a longitudinal section through a first embodiment of an implant according to the invention with added apparatus coupling part.

10 Fig. 2 shows a section through the implant rotated 90° in comparison to Fig. 1, after disconnection of its coupling part, reinstallation thereof and screw tightening thereof.

Fig. 3 shows a section through an implant according to a second embodiment.

Fig. 4 shows a section through all the elements forming part of the second embodiment according to Fig. 3, after disconnection of the implant screw.

15 Fig. 5 shows a section through the assembled implant according to Fig. 4, with mounted apparatus coupling part.

Figs. 6 and 7 show sections through a third and a fourth embodiment of the invention.

Fig. 8 shows a section through a separate first coupling part.

20 DESCRIPTION OF EMBODIMENTS

Figs. 1 and 2, which show a first embodiment of the device according to the invention illustrate this in two different stage, which hereinafter will be described more in detail.

In contrast to the coupling device according to SE-C2-503790 the coupling part 11 of the
25 implant 10 is made integral with the flange fixture 12 of the implant, which fixture consists of a screw 13, which at its lower part is equipped with a chamfer 14, which possibly can form cutting edges, whereas the upper part of the screw continues in a flange 15. Furthermore the flange fixture is provided with an axial blind bore 16 with internal threads 17. The implant continues from the flange 15 and continues in a coupling part 11, hereinafter referred to as the
30 coupling part of the implant, which is formed as a socket and which at its upper, free end edge at the inner side is equipped with an annular bulge 18. The implant is manufactured from a material which is satisfactorily accepted by the human body, e.g. titanium or stainless steel, which means that the socket shaped coupling part 11 is rigid.

The screw 13 of the implant 10 is intended to be screwed into a bore in bone tissue 19, which for instance can be the skull bone, whereby the screw is tightened so deeply that the flange 15 will rest against the bone tissue.

- 5 The transition between the flange fixture 12 of the implant and its coupling part 11 is designed as a material weakening 20, which forms a deformation zone.

10 The second coupling part 21 of the device, hereinafter also referred to as the apparatus part, is connectable with one of its ends to a hearing aid 22, a prosthesis or the like and the other end of which is designed as a male part, which is connectable to the female-shaped coupling part 11 of the implant. For this purpose the apparatus part is designed with a circumferential groove 23, intended to cooperate by snap action with the annular bulge 18 at the coupling part 11 of the implant. The apparatus part 21 is provided with an internal recess 24, whereby also
15 this part is socket-shaped. The resilience of the male part has been achieved by means of a number of axial slots 25, whereby is formed resilient tongues 26. At least some of the tongues 26a are longer than the rest of the tongues 26, which longer tongues at turning of the apparatus part 21 cooperate with at least one ridge-like, raised portion 27, which in the embodiment shown is arranged on the circumferential flange 28 of a releaving member 29, which is partly insertable into the recess 24.

20

As the two coupling parts 11 and 21 are mutually rotatable, at such a rotation the longer tongues 26a will slide up on the ridge 27, whereby the coupling parts will be disconnected from each other.

- 25 If, for any reason, the coupling part 11 of the implant must be removed, e.g. due to skin irritation or due to the fact that it has become damaged or deformed, this can be effected by means of a socket cutter 30, (shown in Fig. 4), whereby a part of the deformation zone 20 can be cut away thus that the coupling part 11 and the apparatus part 21 of the implant are separated. If the coupling part 11 of the implant is not damaged it can be re-used, whereby
30 a sealing ring 32 is positioned in the annular space 31 created by the socket cutter 30, whereupon, by means of a washer 33 and a connecting screw 34, which is screwed into the internal threads 17 of the implant screw 13, is achieved a connection between the parts 11 and 21.

Due to the fact that the coupling part 11 and the flange fixture 12 of the implant are made integral, the operation can be carried out in one stage and be used to full extent after a healing period of a few weeks. Disconnection of the two coupling parts 11 and 21 can be effected in the same simple manner as earlier, by rotating the apparatus part relative to the stationary implant.

Figures 3, 4 and 5 show a somewhat modified embodiment, wherein the release member 29 is redundant and the ridge-like raised portions 27 are arranged at a shoulder 35 inside the socket-shaped coupling part 11. The connecting screw 34 can be designed with such a wide head, that the released first coupling part 11, without intermediary connection of a washer can be screwed together, thereby creating a good physical contact between the parts. By this design the number of components used is reduced with one further part.

Figs. 6 and 7 show an embodiment having a somewhat modified deformation zone, consisting of a transition from the first coupling part 11 to the flange fixture 12, having a Z-shaped cross section. In the same manner as in the previous embodiment, this zone shall have an ability to take up external influence upon the first coupling part in such a manner that only a minor portion of these stresses are transferred elastically to the flange fixture. A portion of the deformation zone 20, e.g. the web of the Z-profile, can be milled away at a necessary dismantling of the main parts 11, 12 of the implant, thus that the parts are separated, with the flange fixture still being affixed in the bone tissue. In order to be able to re-connect these parts it is required a washer 38, which bridges the milled away portion. Thus the lower edge of the first coupling part 11 thereby will be screwed against the washer 38, which can consist of an elastic material, thus that a deformation zone is created after the separation and the subsequent re-connection of the parts. The annular groove 39 between the deformation zone 20 and the flange fixture 12 can be used as a groove for a guiding pin 40 provided at the end of the cutter 30.

Of course it is also possible to substitute the deformed and separated first coupling part 11 for a separate such part, such as shown in Fig. 8, and which does not need to be completed by some loose details, such as the washer 38, as this is built into the coupling part.

The invention is not limited to the embodiments described, but a number of variants are possible within the scope of the claims. Thus the first coupling part of the implant, which in the embodiments shown, is designed as a female part intended to receive the male-shaped second coupling part, can instead be designed as a male part whereas the second coupling part is designed as a female part.

LIST OVER REFERENCE NUMERALS

	10 = Implant
5	11 = First coupling part
	12 = Flange fixture
	13 = Screw
	14 = Chamfer
	15 = Flange
10	16 = Blind bore
	17 = Internal threads
	18 = Annular bulge
	19 = Bone tissue
	20 = Material weakening / Deformation zone
15	21 = 2nd coupling part / Apparatus part
	22 = Hearing aid
	23 = Groove
	24 = Recess
	25 = Slots
20	26 = Short tongue
	26a = Long tongue
	27 = Raised portion/ ridge
	28 = Flange
	29 = Release member
25	30 = Socket cutter
	31 = Annular space
	32 = Sealing ring
	33 = Washer
	34 = Connecting crew
30	35 = Shoulder
	36 = Neck
	37 = Flange
	38 = Washer
	39 = Annular groove
35	40 = Guiding pin

CLAIMS

- 5 1. A device at implants (10) for anchoring in bone tissue (19) and supporting a prosthesis or transfer of electrical and/or mechanical energy from a transmitter (22) or the like to the implant via a coupling device, which incorporates a first and a second coupling part (11, 21),
characterized therein,
that the implant (10), which incorporates a flange fixture (12), is made integral with the first
10 coupling part (11), forming a continuous unit.
2. A device as claimed in claim 1,
characterized therein,
that a deformation zone (20) is provided at the transition between the flange fixture (12) and
15 the first coupling part (11).
3. A device according to claim 2,
characterized therein,
that the deformation zone (20) is arranged at some distance from and substantially in parallel
20 with the flange (15) of the flange fixture, and
that the deformation zone at the same time is a dismounting zone, within which the flange
fixture is separable from the first coupling part, by means of a tool (30) insertable therein.
4. A device according to claim 3,
25 characterized therein,
that the coupling part is separable from the flange fixture (claim 3), which is affixed to the
bone tissue, preferably via a cylindric cutter (30).
5. A device according to claim 3,
30 characterized therein,
that the flange fixture (13) is provided with a central, axial blind bore (16) having internal
threads (17), and that the separated or a new first coupling part (11) is attachable to the flange
fixture (13) and connectable to this by means of a connecting screw (34), which can be
screwed into the said blind bore.

6. A device according to claim 1,
characterized therein,
that in the interior of the socket-shaped first coupling part (11) is attachable a release member
5 (29) equipped with a circumferential flange (37), on which is provided at least one ridge-like
raised portion (27), for cooperation with the end of a tongue (26a) at the second coupling part
(21).

7. A device according to claim 1,
10 characterized therein,
that the interior of the socket-shaped first coupling part (11) is equipped with a shoulder (35)
upon which is formed at least one ridge-like raised portion (27) for cooperation with the end
of at least one tongue (26a) at the second coupling part (21).

15

FIG. 1

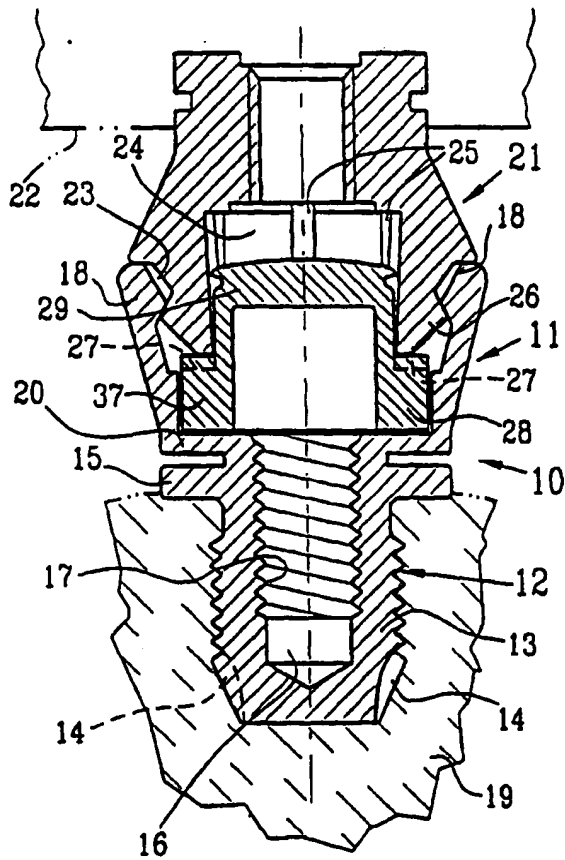


FIG. 2

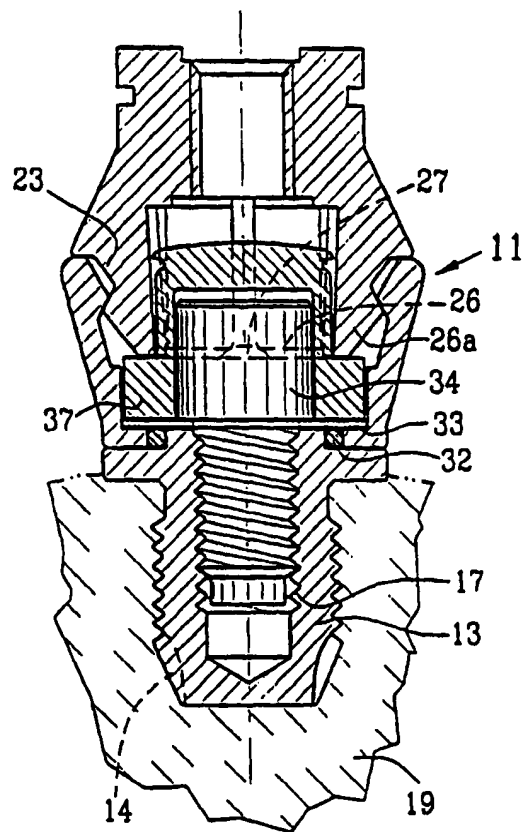


FIG.4

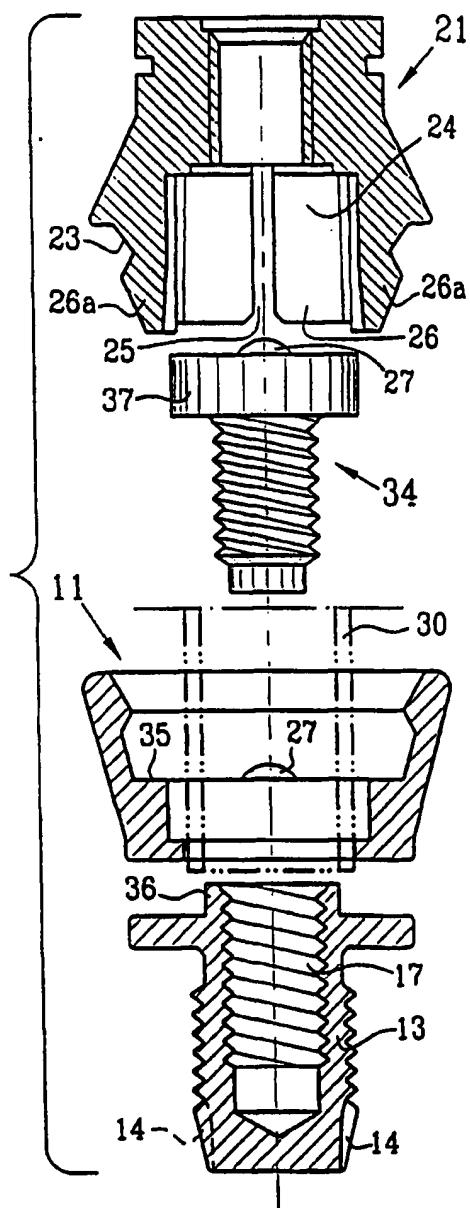


FIG.5

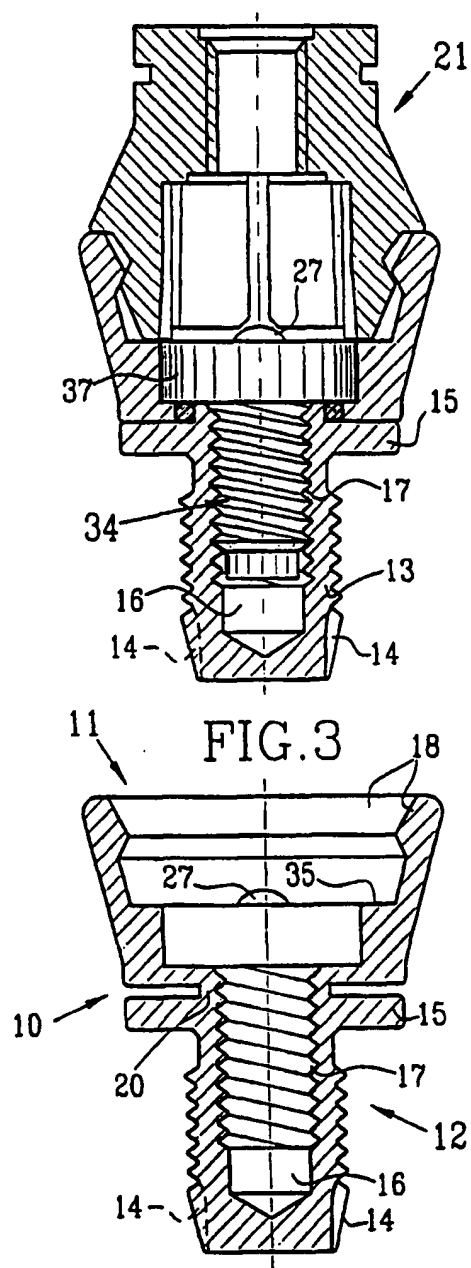


FIG.3

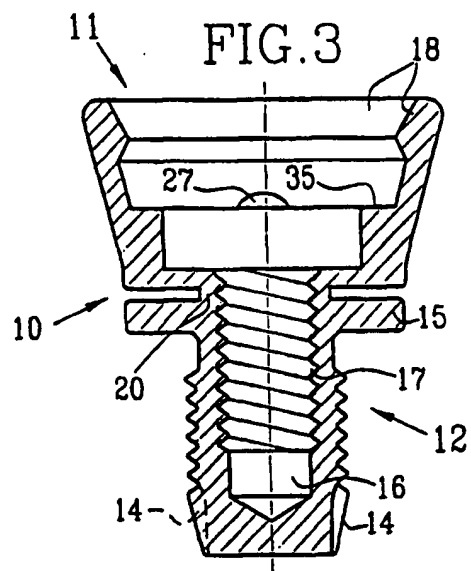


FIG.6

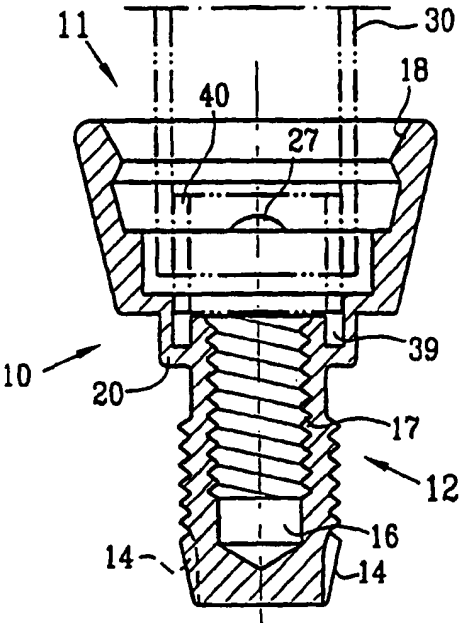


FIG.8

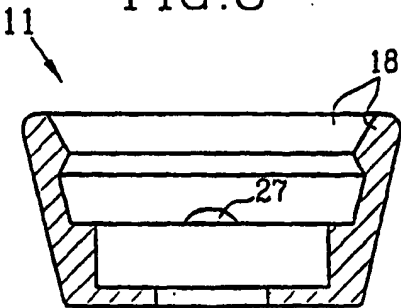
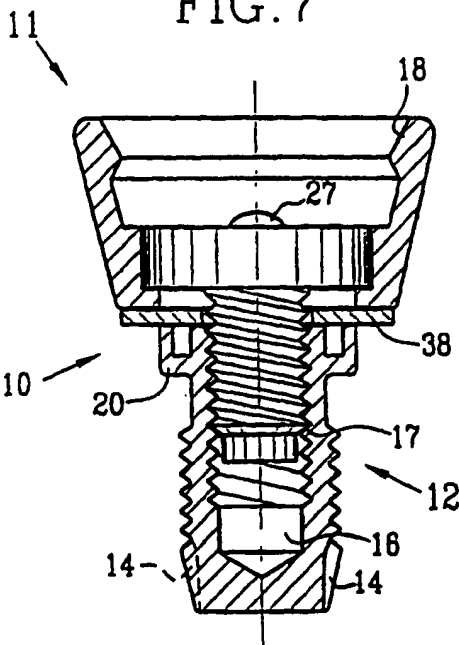


FIG.7



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 98/01049

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/20 // A 61 C 8/00, H 04 R 25/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61C, A61F, H04R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9713477 A1 (NOBEL BIO CARE AB), 17 April 1997 (17.04.97), page 5, line 10 - page 6, line 11, figure 1b --	1
X	US 4328813 A (C.D. RAY), 11 May 1982 (11.05.82), column 2, line 20 - line 63, figures 1-4 --	1
A	EP 0715839 A2 (P & B RESEARCH AB), 12 June 1996 (12.06.96), figure 1 --	1,6-7
A	US 4629451 A (A. WINTERS ET AL.), 16 December 1986 (16.12.86) -- -----	1

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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